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EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,763

Applicant(s)

CAWSE, JAMES NORMAN

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,10,13-15,17-36 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9,10, 13-15, 17-36, and 39-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' arguments filed December 17, 2003 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The cancellation of claims 8, 11, 12, 16, 37, and 38 has been acknowledged.
3. Claims 1-7, 9,10, 13-15, 17-36, and 39-42 are examined on the merits.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-7, 9,10, 13-15, 17-36, and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. This rejection is necessitated by Applicant's amendments.
7. Specific to claims 1, 5, 6, and 7, line 3; claim 2, lines 2-3; claim 35, lines 4-5; and claim 36, line 4, the limitation of "factors comprise a catalyst system and conditions" which causes the claims to be vague and indefinite because it is unclear how factors could comprise "a catalyst system." Further, claim 1 recites at least three factors interactions; it is unclear how "a catalyst system and conditions" are factor interactions or how "a catalyst system and conditions" represent at least three factor interactions. Lastly, the body of the claim is unclear as to how "a catalyst system and conditions" as factors are being used in

accomplishing the intended of goal of the claimed method. Claims 3, 4, 9,10, 13-15, 17-34, and 39-42 are rejected for being directly or indirectly depend from claims 1-3, 6, 7, 35, or 36.

CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-7, 9,10, 13-15, 17-36, and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

10. This rejection is necessitated by Applicant's amendments.

11. Claims 1, 36, lines 13-15; and 35, line 13, recite the limitation of "greater or less than" is considered to be new matter. The support for the limitation of "greater or less than" was not supplied in the claims via "outside of" limitation because the meaning of the phrase "outside of" is different from that of the phrase "greater or less than". It is noted that one of the many interpretations of the phrase "outside of" is "greater or less than." However, that is just one of many ways one of skill in the art could interpret the phrase "outside of." Unless the instant specification defines the phrase "outside of" to mean "greater or less than", the many interpretations of the phrase "outside of" causes said phrase to differ from the phrase "greater or less than." The said limitation has not been found in the instant specification. Claims 2-7,

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9,10, 13-15, 17-34, and 39-42 are rejected for being dependent from claim 1, 36, or 35, respectively.

RESPONSE TO ARGUMENT

12. It is acknowledged Applicant has amended claims 1, 35, and 36 in response to the 35 U.S.C. 112, Second Paragraph rejection, mailed October 9, 2003. However, the said amendment introduces limitations that have not been found in the instant specification, which necessitates said NEW MATTER rejection. Further, it is noted that Applicant states “[i]t is believed that the PTO is proposing this change by including the parenthetical “greater or less than” in the body of the rejection.” The inclusion of the phrase “(greater or less than)” is not a proposal but only to further clarify on the 35 U.S.C. 112, Second Paragraph rejection, mailed October 9, 2003, by examples. The intended use of the phrase “(greater or less than)” is to illustrate that the term “outside” has a plurality interpretations such as positive interaction greater than the deviation or less than the deviation. The plurality of interpretations necessitated the 35 U.S.C. 112, Second Paragraph rejection, mailed October 9, 2003.

CLAIM REJECTIONS - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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14. Claims 1-7, 9, 10, 13-15, 17-28, 34-36, and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrafiotis et al. (US 5,901,069 A) taken with Grate et al. (US 6,408,250 B1).

15. This rejection is maintained with respect to claims 1-7, 9, 10, 13-15, 17-28, 34-36, and 39-42, as recited in the previous office action office action mailed October 29, 2003.

16. This rejection is necessitated by Applicant's amendments.

RESPONSE TO ARGUMENTS

17. Applicant argues that the PTO has not met the burden of establishing a *prima facie* of obvious because the rejection is based on "non-analogous" art, improper combinations of references without the motivation to combine said references, and for the reasons above, no *prima facie* case has been established by the PTO. Applicant's arguments have been fully considered and found to be unpersuasive as discussed below. Further, this response is directed references Agrafiotis et al., Grate et al., and Chaudhari et al.

18. Specific to Applicant's argument directed to the references as being of "non-analogous" art, Applicant is directed to the specification of each patent (Agrafiotis et al., Grate et al., and Chaudhari et al.) wherein Agrafiotis et al. discloses a method of analyzing chemical properties in a sample for performing searches in chemical libraries to identify chemical compounds (Abstract etc. and column 3, lines 31-40), Grate et al. discloses a method for analyzing and generating chemical compounds (Abstract etc.), and Chaudhari et al. discloses a method for analyzing and selection chemicals (Abstract etc.). Therefore, the citations above adequately support that one of ordinary skill in the art at the time of the instant

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invention would look into the references of Agrafiotis et al., Grate et al., and Chaudhari et al. to address the need to generate chemical entities using defined chemical properties.

19. Applicant argues that Agrafiotis et al., Grate et al., and Chaudhari et al. references are not properly combinable for a number reasons. Specifically, “[t]here is not teaching whatsoever in the references of a need to improve on a carbonylation method by “using a matrix algebra analyzed CHTS experiment.” Applicant’s argument (via questions) have been fully considered and found to be unpersuasive as discussed below.

20. Agrafiotis et al. suggests an improvement by disclosing the need for a system and method for efficiently and effectively generating new leads designed for specific utilities. Further, the suggested improvement is directed to generating chemical compounds with desired physical, chemical, and/or biological properties via structure activity models (column 3, lines 27-55). Grate et al. discloses a method for the characterization, classification, identification, and/or quantification of chemical compounds wherein said method directed to using matrix algebra (column 6, lines 59-65) to analyze descriptors such as molecular interaction characteristics, molecular properties, and molecular structure features (column 5, lines 4-24). Therefore, the improvement suggested by Agrafiotis et al. would motivate one of ordinary skill in the art to apply a tool, matrix algebra, for characterizing chemical properties as taught by Grate et al. to the method of Agrafiotis et al. to disclose the invention of the instant application. Further, the improvement suggested by Agrafiotis et al. would motivate one of skill in the art to apply a tool, matrix algebra, for characterizing a catalyst as taught by Grate et al. and Chaudhari et al.

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21. Therefore, the above cited motivation to combine references Agrafiotis et al., Grate et al., and Chaudhari et al. provides an adequate prima case of obviousness to a person of ordinary skill in the art that the teachings of Agrafiotis et al., Grate et al., and Chaudhari et al. in combination suggests the instant claimed subject matter.

22. Specific to Applicant's argument by amendment ("wherein the factors comprise a catalyst system and conditions"), said amendment has been fully considered and found to be unpersuasive due to the vague and indefinite issue caused by said amendment.

23. Specific Applicant's argument that "the references do not establish a prima facie case for items (2) through (10) (pages 13-14, §D) wherein said items have been presented in the previous response, filed October 17, 2003, and the PTO has not responded to said arguments, Applicant's arguments have been fully considered and found to be unpersuasive as discussed below.

24. Applicant's argument as directed to items (2) through (10) (pages 13-14, §D) in the previous response, filed October 17, 2003, via recitation of claim limitations without providing any support through reasoning or pointed to support in the specification has been acknowledged and responded to by the PTO in the previous Office Action, mailed October 29, 2003. Further, Applicant's argument via the recitation of claim limitations without providing any support through reasoning or pointed to support in the specification is neither substantive nor persuasive in overcoming the prior art rejection. Due to Applicant's argument being recitation of claim limitations without providing any support through reasoning or pointed to support in the specification, the PTO has responded to said argument

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by re-iterating the said prior art rejection in the instant Office Action and the previous Office Action, mailed October 29, 2003.

25. Specific to Applicant's argument that the "controller" in the Agraftotis et al. reference is distinct from that of the instant invention, said argument has been fully considered and found to be unpersuasive as discussed below. Agraftotis et al. discloses a computer system comprising a processor and controller as depicted in Figure 1; further, said system performs the computer-aided generation of chemical entities with prescribed set of physical, chemical and/or bioactive properties using a diversity of chemical libraries (column 4, line 65 to column 5, line 5). Grate et al. discloses the use of matrix algebra for characterizing, classifying, and identifying unknowns in a sample (Column 14, equation 10). The system of Agraftotis et al. comprising a processor and controller for the generation of chemical entities and the matrix algebra for characterizing, classifying, and identifying unknowns in a sample of Grate et al. in combination discloses the limitations of claim 39 which depends from claim 36.

26. Specific to Applicant's argument "but A, B, C,...building blocks are not factors of a 'catalyst system'", said argument has been fully considered and found to be unpersuasive due to the limitation of "catalyst system" via amendment introduces the vague and indefinite issue in the amended claims (35 U.S.C. 112, 2nd paragraph rejection above).

27. It is re-iterated that Agraftotis et al. discloses a method of defining an experimental space such as a combinatorial chemical library where a combinatorial chemical library could be constructed from chemical building blocks designated as A, B, and C. Further, the

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compounds in the combinatorial chemical library are equal to two in length, then, the compounds would be generated are: AA, AB,...and CC (total of nine) (column 5, lines 5-18), as in instant claims 2, 3, and 5-7.

28. Agrafiotis et al. discloses said method comprising a linear model (column 17, lines 47-52), as in instant claim 4.

29. The chemical building blocks comprise of 100 commercially available agents (column 5, lines 37-40), as in instant claim 16.

30. The system may perform tests and evaluations on one or more structure-activity models in parallel (column 6, lines 43-45), as in instant claim 23. The method of Agrafiotis et al. performs selective micro scale solid-state synthesis of a specific combinatorial library of directed diversity library (column 8, lines 43-45), as in instant claim 24.

31. The lead generation/optimization system is implemented in an iterative process wherein instructions are sent to a robotic synthesis system and reagents are mixed compounds are synthesized. The said compounds are assayed and ranked; the best-ranked compound is selected (§ Operation of the present invention, columns 13-21) as in instant claims 15, 17, 25-28, and 34.

32. The system of Agrafiotis et al. comprises a processor and controller (Figure 1) wherein the reactions occur defined space of 96 well plates (column 20, lines 51-67), and a detection device (column 10, lines 5-14), as in instant claims 39-42.

33. However, Agrafiotis et al. does not disclose the method of defining experimental space wherein the analysis is done according the steps defined in claims 1, 35 and 36 of this instant application.

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34. Grate et al. discloses the use of matrix algebra for characterizing, classifying, and identifying unknowns in a sample (Column 14, equation 10). Grate et al. defines matrices P containing the coefficients that are related to a plurality of descriptors (column 6, lines 59-65), as in claim 1, step (A).

35. Matrix R where R is equal $C \cdot 10^{(vp+1c)M-1} \cdot N$ (column 7, lines 7 and 8), as in claim 1, step (B) and claim 9. PT is the transpose of matrix P (column 7, lines 16-17 and equations 12-14), as in claim 1, step (C) and claim 10, steps (ii) and (iii).

36. The concentrations are plotted versus the fraction noise (RMSEP) in the data (e.g. 0.1 indicates that the standard deviation of the noise was 10% of the sensor signal) (column 20, lines 35-40 and Figure 1), as in claim 1, steps (i), (ii), and (iii); and claims 35 and 36.

37. The inclusion of a document from Dictionray.com is not intended to be used as prior but only to expand on the standard deviation disclosure of Grate et al. Dictionary.com discloses that it is well know in the art that the calculation of standard deviation is derived from a random variable (page 2, line 10).

38. Further, Grate et al. discloses equations 15-20 (column 15, lines 5-33) in an inverse least approach for descriptor y, as in instant claims 18-22.

39. It is noted that Agrafiotis et al. discloses an improvement for a general system and method for efficiently and effectively generating of chemical entities with defined physical, chemical or bioactive properties for drug lead identification via a chemical library (column 1, lines 15-23 and column 3, lines 27-29). The suggested improvement of Agrafiotis et al. is directly applicable to generation of chemical for the characterization, classifying, and identifying as taught by Grate et al.

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40. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated to partake the concept emphasized by Agrafiotis et al. for an iterative process for generating chemical entities with define physical properties and/or bioactive properties (Abstract etc.) and improve on it by utilizing the method of Grate et al. which comprises using the properties chemical entities to identify a chemical sample. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method of Agrafiotis et al. for generating chemical entities and determining the properties directed to the chemical entities; and identify and characterize the said chemical entities according to the method of Grate et al. which comprises an algebra matrix for identifying a sample.

41. Claims 1-7, 9, 10, 13-36, and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrafiotis et al. (US 5,901,069 A) taken with Grate et al. (US 6,408,250 B1) in view of Chaudhari et al. (US 5,917,077 A).

42. This rejection is maintained with respect to claims 1-7, 9, 10, 13-36, and 39-42, as recited in the previous office action office action mailed September 22, 2003.

43. Agrafiotis et al. discloses a method of defining an experimental space such as a combinatorial chemical library. Further, Grate et al. discloses the use of matrix algebra for characterizing, classifying, and identifying unknowns in a sample (Column 14, equation 10) as directed claims 1-7, 9, 10, 13-28, 34-36, and 39-42 cited above.

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44. However, Agrafiotis et al. taken with Grate et al. does not disclose the limitation of palladium, halide or co-catalysts, which are the embodiments of the above listed instant claim rejected hereunder.

45. Chaudhari et al. discloses a method for preparing chemical entities using catalyst such as the metals of Group IIIB such as palladium and halide (Abstract etc.). Further, the method of Chaudhari et al. includes inorganic co-catalysts (column 1, lines 33-34), as in instant claims 29-33.

46. It is noted that Agrafiotis et al. discloses an improvement for a general system and method for efficiently and effectively generating of chemical entities with defined physical, chemical or bioactive properties for drug lead identification via a chemical library (column 1, lines 15-23 and column 3, lines 27-29). The suggested improvement of Agrafiotis et al. is directly applicable to generation of chemical for the characterization, classifying, and identifying as taught by Grate et al. and Chaudhari et al.

47. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated to partake the concept emphasized by Agrafiotis et al. for an iterative process for generating chemical entities with define physical properties and/or bioactive properties (Abstract etc.) and improve on it by utilizing the method of Grate et al. which comprises using the properties chemical entities to identify a chemical sample such as catalysts (palladium and halide composition) and inorganic catalysts as taught by Chaudhari et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method of Agrafiotis et al. for generating chemical entities and determining the properties as directed to the said chemical entities; and characterize the

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said chemical entities according to the method of Grate et al. using an algebra matrix and improve on the methods of Agrafiotis et al. and Grate et al. by including such chemical entities as catalysts (palladium and halide composition) and inorganic catalysts as taught by Chaudhari et al.

CONCLUSION

48. NO CLAIM IS ALLOWED.

49. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

50. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

51. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

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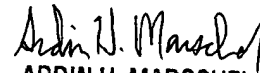
(November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

52. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

53. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

54. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
2/18/04


ARDIN H. MARSCHEL
PRIMARY EXAMINER